

Exhibit E

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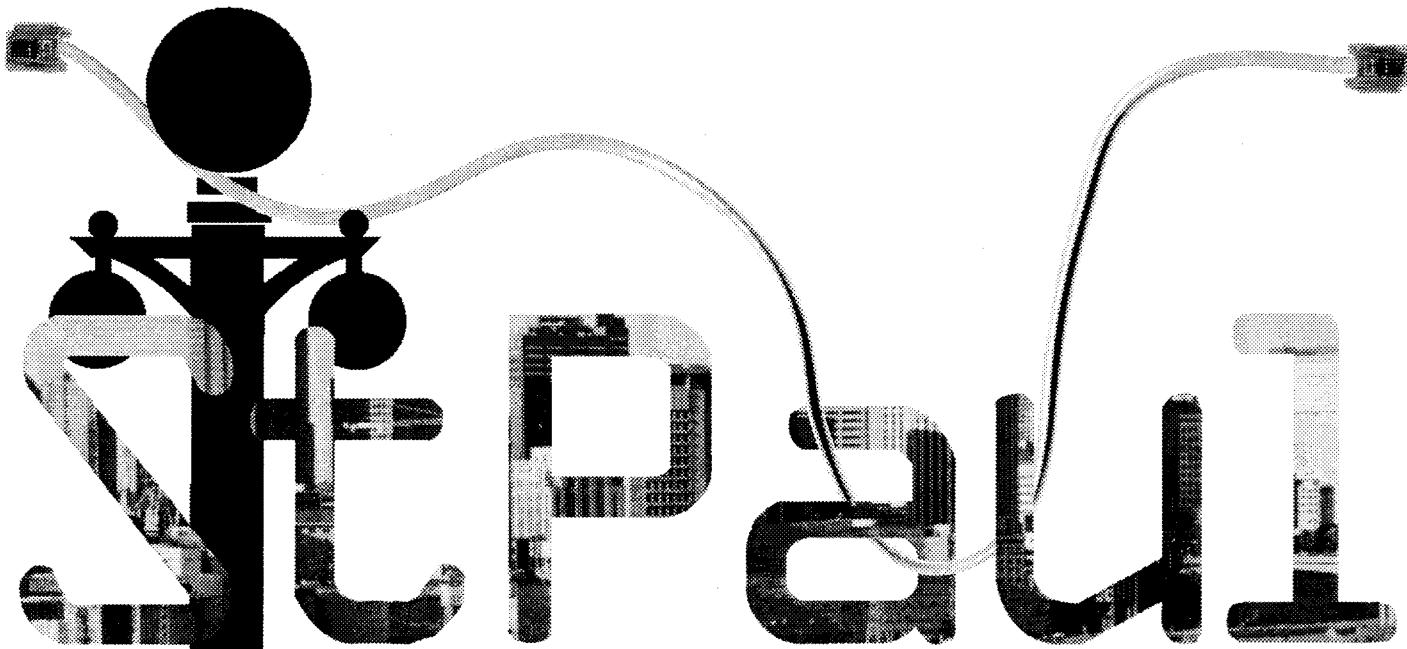
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A 91-Day Tissue Reaction Study of Polypropylene-Based Mesh Materials in Rats

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A subcutaneous implantation study was conducted to assess the tissue reaction profile and qualitative integration of polypropylene-based surgical meshes. PROLENE® Soft mesh was recently developed to provide a lightweight construction surgical mesh that conforms well to irregular surfaces while VYPRO® - Mesh 62 was an early prototype of a composite mesh having an absorbable component of polyglactin 910 filaments. Bard® mesh, a commonly used monofilament surgical mesh, and SURGIPRO® mesh that has a multifilament construction served as comparative controls. Eighty female Long-Evans rats weighing 250 - 300 grams at implantation were randomly distributed into four groups of five rats each for each of four explant periods. The rats were anesthetized, and two transverse incisions, approximately 3 cm in length and 4 cm apart, were made in the skin over the sacral vertebral column. The skin was separated from the underlying connective between these two incisions, and the implant was placed in the pocket. A simple interrupted suture of 4-0 PROLENE® polypropylene suture was placed at each end of the implant to hold it in place to the skin. Skin incisions were closed with metal staples. Rats were euthanized at 7, 28, 63, and 91 days postimplantation by inhalation of carbon dioxide. Photographs of representative implant sites were taken. Each implant site was then preserved in 10% buffered formalin. After fixation, a transverse section perpendicular to the long axis of the implant was trimmed from the central portion of the implant site. The tissue samples were then processed, embedded in paraffin, and stained with hematoxylin and eosin for histomorphologic evaluation. Tissue reaction to the implants and assessment of integration (fibrosis) were evaluated semi-quantitatively by considering the amount and extent of each response on a scale of 0 – 4 where 0 = normal/negligible, 1 = minimal, 2 = mild, 3 = moderate, and 4 = marked. For Bard® mesh at 7 days postimplantation, the tissue reaction was characterized by mild chronic inflammation and fibrosis. Chronic inflammation consisted of lymphocytes and macrophages with some foreign body giant cells surrounding the implant. At 28, 63, and 91 days postimplantation, the tissue reaction was characterized by minimal to mild chronic inflammation, and minimal or minimal to mild fibrosis. The mean fibrosis scores were 1.0, 1.6, and 1.8 at 28, 63, and 91 days postimplantation, respectively. For SURGIPRO® mesh at 7 days postimplantation, the tissue reaction was characterized by minimal to mild foreign body reaction and fibrosis, although the fibrosis was predominately minimal. Foreign body reaction consisted of foreign body giant cells with lymphocytes and macrophages surrounding the implant. At 28, 63, and 91 days postimplantation, the tissue reaction was characterized by mild foreign body reaction, and minimal

or minimal to mild fibrosis. The mean fibrosis scores were 1.0, 1.2, and 1.0 at 28, 63, and 91 days postimplantation, respectively. For PROLENE Soft mesh at 7 days postimplantation, the tissue reaction was characterized by minimal to mild chronic inflammation and mild fibrosis. At 28, 63, and 91 days postimplantation, the tissue reaction was characterized by mild chronic inflammation, and minimal to mild fibrosis. The mean fibrosis scores were 1.4, 1.4, and 1.2 at 28, 63, and 91 days postimplantation, respectively. For VYPRO - Mesh 62 at 7 days postimplantation, the tissue reaction was characterized by mild to moderate foreign body reaction and mild fibrosis. At 28, 63, and 91 days postimplantation, the tissue reaction was characterized by mild foreign body reaction, and minimal or minimal to mild fibrosis. The mean fibrosis scores were 1.8, 1.0, and 0.8 at 28, 63, and 91 days postimplantation, respectively. Overall, the inflammatory reaction to polypropylene-based surgical meshes of different construction was relatively similar, ranging from minimal to mild in intensity, and they were all considered to be biocompatible. All of the meshes had sufficient porosity to allow for ingrowth of the surrounding connective tissue. The implantation of Bard® mesh, a relatively stiff monofilament mesh, resulted in generally mild fibrosis. The implantation of SURGIPRO® mesh resulted in generally minimal fibrosis at all time periods. It is possible that the flexibility of this multifilament mesh played a role in this result by inciting less mechanical irritation to surrounding tissue. The implantation of PROLENE® Soft mesh resulted in mild fibrosis at 7 days postimplantation. The fibrosis decreased over the following time periods such that the intensity at 91 days postimplantation was minimal. The implantation of VYPRO® - Mesh 62 resulted in mild fibrosis up to 28 days postimplantation, decreasing to minimal fibrosis at 63 and 91 days postimplantation. The reduction in the intensity of fibrosis coincided with the loss of polyglactin 910 filaments by hydrolysis and subsequent absorption between 63 and 91 days postimplantation. The observation of mild fibrosis with these polypropylene-based meshes is consistent with that observed historically, and to that generally reported in the literature. Based on a long history of successful clinical use, it is expected that this degree of fibrosis in an animal model is sufficient to predict a successful clinical outcome. Histomorphologic results suggest that a minimal degree of fibrosis is adequate to ensure appropriate integration of the mesh, although further studies would be necessary to more quantitatively determine the contribution of tissue ingrowth to the physical strength of the mesh.

*Trademarks of Ethicon, Inc.